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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,555	08/26/2003	Hans Muller	P 1035.13004	5522

30615 7590 11/01/2005

BIRDWELL & JANKE, LLP
1100 SW SIXTH AVENUE
SUITE 1400
PORTLAND, OR 97204

EXAMINER	
DEAK, LESLIE R	

ART UNIT	PAPER NUMBER
3761	

DATE MAILED: 11/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/649,555	MULLER, HANS	
	Examiner	Art Unit	
	Leslie R. Deak	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 10/048,693.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The abstract of the disclosure is objected to because it fails to provide a complete summary of the invention. Correction is required. See MPEP § 608.01(b).

Information Disclosure Statement

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1, 3, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,093,108 to Hein et al in view of US 5,674,195 to Truthan.

Hein discloses in the specification and figures substantially the device claimed by applicant. In particular, Hein discloses a syringe with a cylindrical body 1 and a

converging end and tip 15 at the distal end (see FIG 1, column 3, generally). The syringe further comprises a hollow piston rod 3 indicating the rod has a bore therethrough, a tip at the top end of the piston rod, and a valve 5 at the distal end of the piston rod (see FIG 1). Shoulder or stop 14 acts as a locking device, since it prevents further movement of the piston. Piston 2 of the Hein device serves as applicant's cap seal structure, with bore 26 provided through the cap seal, providing access to interior space 8 between the cap seal 2 and valve 5.

With regard to applicant's claim limitation drawn to multiple holes in the cap seal structure (Hein discloses only one such hole), it has been held that duplication of the essential working parts of a device involves only routine skill in the art. See MPEP 2144.04. With regard to applicant's claim drawn to the size and placement of the holes in the cap seal, it has been held that changing the size and placement of parts of a prior art device requires only routine skill in the art. See MPEP 2144.04.

With regard to applicant's recitation of the operation of the device (see claims 1, 9), such limitations are held to be a recitation of the intended use of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, the Hein device substantially satisfies the instantly claimed structural limitations and is disclosed as capable of creating a pressure differential within the cylinder barrel 1 in order to move fluid therethrough (see column 4, lines 5-21).

Hein fails to disclose that the hollow piston rod is substantially cross-shaped. Cross-shaped syringe pistons are well-known in the art, including those with bores therethrough.

Truthan discloses a syringe with a cylindrical barrel 12, converging tip 26, cross-shaped plunger 14 with central passage 20 and cover 18 (see FIG 1, column 2, lines 33-55). It would have been an obvious matter of design choice at the time the invention was made to substitute the cross-shaped plunger with central passage disclosed by Truthan for the hollow-rod piston structure disclosed by Hein, since applicant has not disclosed that the cross-shape of the plunger solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with the hollow piston rod disclosed by Hein. See MPEP 2144.03.

5. Claims 2 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,093,108 to Hein et al in view of US 5,674,195 to Truthan as applied above, further in view of US 4,711,637 to Leigh et al.

Hein and Truthan disclose the apparatus substantially as claimed with the exception of a U-shaped locking disk

Leigh discloses a syringe with a cylindrical barrel 10, a flange 26, and a U-shaped lock 26 that may be placed on the flange (see FIGS 1-2). The lock comprises legs such as 36a that engage with the recesses of the cross-shaped plunger 14 (see FIG 5). The lock allows the plunger to be locked in any desired position with relation to the cylindrical barrel (see column 1, lines 50-53). With regard to claim 4, the recesses in the cross-shaped piston rod of the Leigh device extend along the entire length of the

rod, making the recesses capable of locking the plunger at various syringe fill volumes or at the fully extended position.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the syringe disclosed by Hein and Truthan with the U-shaped locking disc disclosed by Leigh in order to lock the plunger in any position relative to the barrel, as taught by Leigh.

6. Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,093,108 to Hein et al in view of US 5,674,195 to Truthan as applied above, further in view of BR 9505028A to Bracco.

Hein and Truthan disclose the device substantially as claimed with the exception of cut-outs in the piston rod and a resilient locking arm. Bracco discloses a suction syringe with a cylindrical barrel 1 and cross-shaped plunger 5 with preformed nicks or cut-outs 7 in opposite sides of the rod web. The cut-outs may be engaged with a spring lock (not pictured) in order to retain the plunger in a predetermined position within the barrel. The spring lock disclosed by Bracco acts as an insertion pin, since the lock inserts itself within the cutout 7, as well as a resilient arm, since springs are, by their very nature, resilient.

Therefore, it would have been obvious to provide the syringe as disclosed by Hein and Truthan with the cut-outs and resilient spring lock as disclosed by Bracco in order to retain the plunger in predetermined positions with relation to the barrel.

With regard to applicant's claim drawn to the placement of the cutouts in the piston rod, it has been held that rearranging the parts of a prior art device requires only routine skill in the art. See MPEP 2144.04.

7. Claims 5 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,093,108 to Hein et al in view of US 5,674,195 to Truthan as applied above, further in view of US 5,528,923 to Ledez et al.

Hein and Truthan disclose the apparatus substantially as claimed with the exception of connecting the syringe to an oxygen source and adding oxygen to the main compartment of the syringe. Generally, a recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138. Furthermore, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. However, in the interest of compact prosecution, Examiner will address the claim limitations under the assumption that applicant intends to claim a device that allows oxygen to be added to the syringe.

Ledez discloses a syringe with a cylindrical barrel 301 with a flanged 303 end, plunger 314 with a vertical bore 315 therethrough, and an aperture at the end of the plunger (see column 13, lines 45-67, column 14, lines 1-21, FIG 3). The plunger is further equipped with an adapter 324 that connects to a gas injection tube 334. The syringe with gas introduction means disclosed by Ledez allows for gas introduction

directly into the aspiration vessel without requiring an intermediate containment vessel, preventing errors (see column 1, lines 39-45).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to add a gas introduction apparatus as disclosed by Ledez to the syringe disclosed by Hein and Truthan in order to provide a gas introduction means that does not require a secondary containment vessel, reducing the chance of handling errors, as taught by Ledez.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

a. US 4,361,155 , Anastasio

i. Blood sampling unit with syringe and hollow plunger

b. US 4,685,910 Schweizer

ii. Syringe with hollow plunger and lock

c. US 5,697,915 Lynn

iii. Syringe with check valve

d. EP 254765 A1 Vetter

iv. Syringe with hollow plunger and valve

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leslie Deak
Patent Examiner
Art Unit 3761
27 October 2005